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| 1444 7590 02/22/2008<br>BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      |                     |                  |
| EXAMINER<br>MAKAR, KIMBERLY A  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1636   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/520,008

**Applicant(s)**

CAO ET AL.

**Examiner**

Kimberly A. Makar, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-10 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-10, 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/05/07 has been entered.
2. Applicants have cancelled claims 1-2 and 11-16. Applicants have added new claims 17-27. Currently, claims 3-10, 17-27 are pending and under examination. In the previous office action, claims 1, and 7-10 were rejected under 35 U.S.C. 102(e) as being anticipated by Graham (US Patent 6,573,099). Claims 5-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US Patent 6,573,099) and Robbins et al (Viral Vectors for Gene Therapy. Pharmacology, 1998.80(1):35-47). Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US Patent 6,573,099 in view of Wengel et al (WO 99/14226) (of record 12/30/04).
3. The art rejections are withdrawn in light of applicant's amendments narrowing the scope of the claims to "consisting" claim language, which does not allow for any nucleic acid sequences outside of the inverse repeat sense and antisense segments.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 3-10, 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended/added claims (17-18) recite the phrase preparing a DNA which "consists" of an inverted repeat sequences. The instant specification does not utilize the term "consist" or "consists" or "consisting of" except in one circumstance, in which the specification states "Such a DNA consists of several hundreds to several thousands of nucleotides and contains nucleotides for repairing the plurality of mutant nucleotides in the target nucleic acid within a region of several hundreds to several thousands of nucleotides" and thus is not used to delineate structural requirements to the inverted repeat sequences, as used in the newly proposed claims. The instant specification teaches a method of introducing a mutation into a cell by preparing a DNA comprising inverted repeat DNAs, 0-0 irDNA, 0-2 irDNA and 0- 6 irDNA, which were prepared by PCR using pucGFP0-0, pucGFP0-2 and pucGFP0-6 as templates (see page 23 of the instant specification). However the instant specification does not provide a structural analysis or map of 0-0 irDNA, 0-2 irDNA and 0- 6 irDNA to demonstrate that they are indeed examples of a DNA which "consists" of the specific claimed elements of the instant claims 17 and 18, and *no additional elements of the plasmids from which the irDNA were PCR amplified*. Thus the instant claims now recite a limitation, which was not clearly disclosed in the specification as

filed, and now changes the scope of the instant disclosure as filed. Such a limitation recited in the present claims, which did not appear in the specification as filed, introduces new concepts and violates the description requirement of the first paragraph of 35 U.S.C. 112. THIS IS A NEW MATTER REJECTION.

***Response to Arguments***

6. Applicant's arguments filed 11/05/07 have been fully considered but they are not persuasive. Applicant's argue 1) the claims language "consisting of" and "comprising" are "discouraged from being used in the specification by the USPTO, that it is common practice to limit the claims, even if such language is not used in the specification, in order to differentiate between open and closed claim language". Applicants later argue that the use of such closed language provided excludes anything outside of the inverted repeat sequence, including a promoter.

7. The examiner is not persuaded by applicant's arguments. The examiner is unaware of applicant's assertion that the USPTO discourages the practice of using transitional phrases within the specification, and invites applicant to provide a reference in the MPEP or official gazette where such teachings can be found. However, the MPEP is quite specific regarding that the claim language, "comprising" or "consisting of" represent legally defined transition phrases. MPEP 2111.03 teaches:

**2111.03 Transitional Phrases [R-3]**

The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited

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elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). *In Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." *Id.* In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. *Id.* The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. *Id.*

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). But see *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32, 70 USPQ2d 1508, 1516 (Fed. Cir. 2004) (holding that a bone repair kit "consisting of" claimed chemicals was infringed by a bone repair kit including a spatula in addition to the claimed chemicals because the presence of the spatula was unrelated to the claimed invention). A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986). >See also *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004) (The claims at issue "related to purified DNA molecules having promoter activity for the human involucrin gene (hINV)." *Id.*, 73 USPQ2d at 1365. In determining the scope of applicant's claims directed to "a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion consists of the nucleotide sequence from ... to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity," the court stated that the use of "consists" in the body of the claims did not limit the open-ended "comprising" language in the claims (emphases added). *Id.* at 1257, 73 USPQ2d at 1367. The court held that the claimed promoter sequence designated as SEQ ID

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NO:1 was obtained by sequencing the same prior art plasmid and was therefore anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. *Id.* at 1256 and 1259, 73 USPQ2d at 1366 and 1369. The court affirmed the Board's interpretation that the transition phrase "consists" did not limit the claims to only the recited numbered nucleotide sequences of SEQ ID NO:1 and that "the transition language 'comprising' allowed the claims to cover the entire involucrin gene plus other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO:1 recited by the claim[s]" *Id.* at 1256, 73 USPQ2d at 1366.<

8. The instant specification teaches a method of introducing a mutation into a cell by preparing a DNA comprising inverted repeat DNAs, 0-0 irDNA, 0-2 irDNA and 0- 6 irDNA, which were prepared by PCR using pucGFP0-0, pucGFP0-2 and pucGFP0-6 as templates (see page 23 of the instant specification). However the instant specification does not provide a structural analysis or map of 0-0 irDNA, 0-2 irDNA and 0- 6 irDNA to demonstrate that they are indeed examples of a DNA which "consists" of the specific claimed elements of the instant claims 17 and 18, and *no additional elements of the plasmids from which the irDNA were PCR amplified*. Thus because the instant specification does not support the language "consists of" in regards to the structural elements of the DNA required in the claimed methodology, and there is no specific examples which clearly demonstrate that applicant's have provided a specific example of the claimed genus, the instant claims introduces new concepts and violates the written description requirement.

### ***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/02/15/08

/Joseph T. Woitach/  
Supervisory Patent Examiner, Art Unit 1633